DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-295/SLR-060

Mallinckrodt Inc.
Attention: Robert F. Ingham
Regulatory Affairs-Imaging
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Ingham:

Please refer to your supplemental new drug application dated March 15, 2002, received March 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CONRAY® 43 (Iothalamate Meglumine Injection U.S.P. 43%).

We acknowledge receipt of your submissions dated September 25, and December 13, 2002, and June 12, 2003. Your submission of December 13, 2002, constituted a complete response to our September 13, 2002, action letter.

This supplemental new drug application provides for combining the urographic indications of Cysto-CONRAY® with the intravascular indications of CONRAY® 43 under the CONRAY® 43 name. Our September 13, 2002, action letter stated that before this supplemental application may be approved, you must either submit revised labeling with a Pregnancy Category C that includes all previous revisions, as reflected in the most recently approved package insert, or, alternatively, submit data for segment I and II reproductive toxicity that comply with current standards to support Pregnancy Category B.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We remind you of your commitment in your June 12, 2003, letter to make the revisions as stated in our facsimile dated June 6, 2003.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted December 13, 2002), with the changes identified in our June 6, 2003, facsimile.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 13-295/SLR-060." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lynn Panholzer, Pharm.D., Regulatory Project Manager, at (301) 827-3247.

Sincerely,

{See appended electronic signature page}

Florence Houn, M.D., M.P.H.
Acting Division Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sally Loewke
6/13/03 12:32:53 PM
Signing for F. Houn